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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|---|-------------|----------------------|---------------------|------------------|
| 10/714,781 | 11/17/2003 | Sheena May Loosmore | 454313-3161.5 | 2429 |
| 20/999 7590 05/06/2008 FROMMER LAWRENCE & HAUG 745 FIFTH AVENUE- 10TH FL. NEW YORK, NY 10151 | | | | |
| EXAMINER | | | | |
| MOSHER, MARY | | | | |
| ART UNIT | | PAPER NUMBER | | |
| 1648 | | | | |
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/714,781

Applicant(s)

LOOSMORE ET AL.

Examiner

Mary E. Mosher, Ph.D.

Art Unit

1648

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 10/31/07.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-22 and 30 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-22 and 30 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☒ None of:
1. ☒ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/CDC)
- Paper No(s)/Mail Date _____

- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date _____
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____

DETAILED ACTION

The examiner of your application in the USPTO has changed. To aid in correlating any papers for this application, all further correspondence regarding this application should be directed to Art Unit 1648, examiner Mosher.

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 10/31/2007 has been entered.

Response to Amendment

The rejection of claims 18-20 and 22 under 35 USC 112, 2nd paragraph is withdrawn in view of the amendment to the claims.

The objection to claim 10 is withdrawn in view of the amendment to the claim.

The provisional double patenting rejection over claims of copending application 10/676502 is withdrawn in view of the abandonment of that application.

Claim Rejections - 35 USC § 102

Claims 1, 7, 10-12, 16, and 30 are rejected under 35 U.S.C. 102(e) as being anticipated by Kinney et al WO 01/60847, see example 6. This rejection is **REINSTATED** because withdrawal of the rejection was in error. Applicant argued that the reference was not available as prior art because it was filed August 23, 2001, which

is later than applicant's priority date, and the rejection was withdrawn in response to that argument. However, Kinney was not filed on August 23, 2001, but on February 23, 2001, which is earlier than applicant's priority date. Therefore the rejection is

REINSTATED.

Claims 1-3, 7, 16, and 30 are rejected under 35 U.S.C. 102(b) as being anticipated by Yamshikov et al (Gene 149:193-201). This rejection is **REINSTATED** because withdrawal of the rejection was in error. Applicant argued that amendment of the claims to recite a vaccine inherently provides information relating to the characteristics of the composition, that a protective immune response is conferred by administration of the vaccine composition. However, the ability to induce a protective immune response is also inherent in the composition disclosed by Yamshikov, since it contains the same components as the composition recited in the claims. Insufficient understanding of the inherent properties of a known composition does not defeat a finding of anticipation. *Atlas Powder Co. v. IRECO Inc.*, 51 USPQ2d 1943.

Claims 1, 7, 16-22, and 30 are rejected under 35 U.S.C. 102(e) as being anticipated by Chang et al US 2003/0022849, for reasons of record. Claim 7 is added to this rejection, as it was previously omitted by error. Applicant has not filed any showing of prior invention. Note, the Chang application has now issued as patent 7227011.

Claim Rejections - 35 USC § 103

Claims 17 and 18 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kinney et al WO 01/60847, for the reasons given in the first Office action. This rejection is **REINSTATED** because Kinney is available as prior art, as discussed above.

Claims 10-13 remain rejected under 35 U.S.C. 103(a) as being unpatentable over Chang et al 2003/0022849, for reasons of record. Again, applicant has not filed any showing of prior invention.

Claims 1-13, 15-18, 20, and 30 remain rejected under 35 U.S.C. 103(a) as being unpatentable over the combined teachings of Paoletti et al 5,744,141, Chang US2003/0022849, and Paoletti 5,505,941, for reasons of record.

Claims 21, 22 remain rejected under 35 U.S.C. 103(a) as being unpatentable over the combined teachings of Paoletti et al 5,744,141, Chang US2003/0022849, and Paoletti 5,505,941 as applied to claims 1-32, 36 above, and further in view of Ramshaw et al (Immunology Today 21:163-165, 2000), for reasons of record.

Claims 14, 19 remain rejected under 35 U.S.C. 103(a) as being unpatentable over Paoletti et al 5,744,141, Chang US2003/0022849, and Paoletti 5,505,941 as applied to claims 1-32, 36 above, and further in view of Audonnet et al WO 99/44633, for reasons of record. Applicant has not presented a showing that the publication by Audonnet is not by another.

Claims 1-11, 16-18 22, and 30 remain rejected under 35 U.S.C. 103(a) as being unpatentable over Paoletti (Proc Natl Acad Sci USA, 1996, 93:11349-11353), in view of both Goverdhan et al. (Acta Virol, 1992, 36: 277-283) and Ostlund et al. (Vet Clin North

Am Equine Pract, 2000, 16: 427-44, Abstract), as evidenced by Paoletti et al. (US Patent No. 5,756,103), for reasons of record.

Claims 1-12, 16-18, 22, and 30 remain rejected under 35 U.S.C. 103(a) as being unpatentable over Paoletti taken with Goverdhan et al. and Ostlund et al., as applied to claims 1-11, 16-18, and 22 above, in further view of both Stocks et al. (J Virol, 1998, 72: 2141-2149) and Chang et al. (J Virol, 2000, 74: 4244-4252), for reasons of record.

Claims 1-11, 13, 14, 16-20, 22, and 30 remain rejected under 35 U.S.C. 103(a) as being unpatentable over Paoletti taken with Goverdhan et al. and Ostlund et al., as applied to claims 1-11, 16-18, and above, in further view of Mumford et al. (Epidemiol Infect, 1994, 112: 421-437, Abstract), for reasons of record.

Claims 1-11, 15-18, 22, and 30 remain rejected under 35 U.S.C. 103(a) as being unpatentable over Paoletti taken with Goverdhan et al. and Ostlund et al., as applied to claims 1-11, 16-18, and 22 above, in further view of Varga et al. (Veterinary Microbiol, 1997, 56: 205-212), for reasons of record.

Claims 1-11, 16-18, 21, 22, and 30 remain rejected under 35 U.S.C. 103(a) as being unpatentable over Paoletti taken with Goverdhan et al. and Ostlund et al., as applied to claims 1-11, 16-18, and 22 above, in further view of Ruitengerg et al. (Vaccine, 2000, 18:1367-1373), for reasons of record.

In response to the above rejections, applicants argue that one would not extrapolate from pigs to horses, that killed and live vaccines are different, and that the references would lead one to administer a JEV vaccine against WN since Goverdhan teaches cross-protection. However, extrapolation from one species to another is

commonplace, as evidenced by the routine testing of vaccines and therapies in animal models. Paoletti teaches an effective anti-JEV vaccine, Goverdhan teaches very close similarity between JEV and WN, and Ostlund provides motivation to combine. The real-world success of example 32 has been considered, but the arguably unexpected single-dose protection in horses is not commensurate in scope with the composition and method as claimed.

Double Patenting

Claims 1-22 and 30 remain provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-30 of copending application 10/679520, for reasons of record. Applicant's intent to address the rejection is noted.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Mary E. Mosher, Ph.D. whose telephone number is 571-272-0906. The examiner can normally be reached on varying dates and times; please leave a message.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Bruce Campbell can be reached on 571-272-0974. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Mary E Mosher, Ph.D./
Primary Examiner, Art Unit 1648

5/5/08